

WE CLAIM:

1. A method of controlling or preventing epileptic seizures comprising the steps of:
 - (a) implanting a signal generator in a body;
 - (b) implanting at least one electrode to be in communication with a vagus nerve of said body;
 - (c) coupling said one or more electrodes to said signal generator;
 - (d) operating the signal generator to provide stimulation pulses to the vagus nerve via the electrodes;
 - (e) generating a sensor signal indicative of a characteristic of a heart; and
 - (f) regulating said stimulation pulses in response to said sensor signal, whereby epilepsy is treated.
2. A method, as claimed in claim 1, wherein said step of regulating comprises the step of executing a control algorithm.
3. A method as claimed in claim 1, wherein said step of generating a sensor signal provides instantaneous heart rate information.
4. A method as claimed in claim 1, wherein said step of generating a sensor signal provides heart rate variability information.

5. A method as claimed in claim 1, wherein said step of implanting the electrode include the step of positioning the electrode to selectively stimulate slow conducting vagus nerve fibers.

6. A method as claimed in claim 1, wherein the step of regulating includes the step of adjusting at least one characteristic of the stimulation pulses, wherein the characteristic is selected from the group consisting of pulse shape, inter-stimulus interval, pulse frequency, pulse width, pulse amplitude, and pulse phase.

7. A method as claimed in claim 1, wherein the step of operating the signal generator is performed in response to a sensing of a possible onset of a seizure.

8. A method as claimed in claim 1, wherein the step of operating the signal generator is performed in response to a user operating a switch to activate the signal generator.

9. A system for controlling or preventing epileptic seizures comprising in combination:
- (a) an implantable signal generator providing stimulation energy;
 - (b) at least one electrode having a proximal end coupled to said signal generator and a distal end adapted to provide stimulation to a vagus nerve of a patient;
 - (c) a sensor for generating a sensor signal indicative of a characteristic of a heart; and

- (d) control means responsive to said sensor signal for regulating said stimulation.
10. The system of claim 9 further comprising:
- (e) a switch coupled to the signal generator and operable by the patient, whereby the patient may manually turn on or off the vagus nerve stimulation.
11. The system of claim 9, further comprising:
- (e) a second sensor generating a second sensor signal indicative of a possible onset of a seizure, and wherein the signal generator is responsive to the second sensor signal.
12. The system of claim 11, wherein the second sensor is implantable to be in communication with a brain of the patient.
13. The system of claim 9, wherein the signal generated by the sensor is selected from the group consisting of an instantaneous heart rate (IHR) signal and a heart rate variability signal.
14. The system of claim 9, wherein the signal generated by the sensor is of heart pulse.
15. The system of claim 9, wherein the signal generated by the sensor is of a rate of change of a heart pulse.

16. The system of claim 9, wherein the signal generated by the sensor is an electrocardiogram (EKG) of a patient.

17. A method of controlling or preventing epileptic seizures comprising the steps of:

- (a) implanting a signal generator in a body;
- (b) implanting at least one electrode to be in communication with a vagus nerve of said body;
- (c) coupling said one or more electrodes to said signal generator;
- (d) operating the signal generator to provide stimulation pulses to the vagus nerve via the electrodes;
- (e) detecting a characteristic of a heart; and
- (f) regulating said stimulation pulses in response to said step of detecting, whereby epilepsy is treated.

18. A method of minimizing effects to a heart of a patient during vagus nerve stimulation comprising the steps of:

- (a) measuring a characteristic of a heart selected from the group consisting of an instantaneous heart rate (IHR) and a heart rate variability;
- (b) determining whether the measured characteristic of the heart is within a normal range for the patient; and

- (c) if the heart is operating outside the normal range, adjusting stimulation of a vagus nerve to bring the heart within the normal range.

19. The method of claim 18, wherein the step of adjusting stimulation includes the step of adjusting at least one characteristic of stimulation pulses provided to the vagus nerve, wherein the characteristic is selected from the group consisting of pulse shape, inter-stimulus interval, pulse frequency, pulse width, pulse amplitude, and pulse phase.

20. The method of claim 18, wherein the step of adjusting includes the step of turning off stimulation to the vagus nerve.

21. The method of claim 18, further comprising the step of:

- (d) operating a pacemaker to maintain the heart within the normal range.

22. The method of claim 18, further comprising the step of:

- (d) alerting the patient by way of a sensory signal.

23. The method of claim 22, wherein the step of alerting includes the step of providing an audio signal to the patient.

24. The method of claim 22, wherein the step of alerting includes the step of

providing a vibrating signal to the patient.

25. A method of minimizing effects to a heart of a patient during vagus nerve stimulation comprising the steps of:

- (a) measuring a characteristic of a heart selected from the group consisting of an instantaneous heart rate (IHR) and a heart rate variability;
- (b) determining whether the measured characteristic of the heart is within a normal range; and
- (c) if the heart is operating outside the normal range, alerting the patient by way of a sensory signal of effects to the heart caused by the vagus nerve stimulation.

26. The method of claim 25, wherein the step of alerting includes the step of providing an audio signal to the patient.

27. The method of claim 25, wherein the step of alerting includes the step of providing a vibrating signal to the patient.

28. The method of claim 25, further comprising the step of:

- (d) operating a pacemaker to maintain the heart within the normal range.

29. The method of claim 25, further comprising the step of:

- (d) turning off stimulation to the vagus nerve.

30. A method of minimizing effects to a heart of a patient during vagus nerve stimulation comprising the steps of:

- (a) implanting a signal generator in a body of a patient;
- (b) implanting at least one electrode to be communication with a vagus nerve of the body;
- (c) coupling that at least one electrode to the signal generator;
- (d) identifying at least one phase of a heart pulse during which vagus nerve stimulation has reduced effect on the heart; and
- (e) programming the signal generator to provide stimulation only during the at least one phases of the heart pulse.

31. The method of claim 30, further comprising the step of:

- (f) sensing an indication of a possible onset of a seizure.

32. The method of claim 31, wherein the step of sensing includes the step of sensing an electroencephalogram (EEG) of a patient.

33. The method of claim 31, wherein the step of sensing includes the step of sensing a cortical signal.

34. The method of claim 31, wherein the step of sensing includes the step of sensing an electrocardiogram (EKG) of a patient for an indication of a possible onset of a seizure.

35. The method of claim 31, wherein the step of sensing includes the step of sensing a characteristic of a heart selected from the group consisting of an instantaneous heart rate (IHR) and a heart rate variability

36. The method of claim 31, further comprising the step of:

(g) if a possible seizure onset is detected, providing a warning of the possible seizure onset.

37. The method of claim 36, wherein the step of warning includes the step of providing an audio signal.

38. The method of claim 36, wherein the step of warning includes the step of providing a vibrating signal.

39. The method claim 30, further comprising the steps of:

(f) determining whether the measured characteristic of the heart is within a normal range;
and

(g) if the heart is operating outside the normal range, alerting the patient by way of a sensory signal.

40. The method claim 30, further comprising the steps of:

(f) determining whether the measured characteristic of the heart is within a normal range;
and

(g) if the heart is operating outside the normal range, adjusting stimulation of a vagus nerve to bring the heart within the normal range.

41. The method claim 30, further comprising the steps of:

(f) determining whether the measured characteristic of the heart is within a normal range;
and

(g) if the heart is operating outside the normal range, turning off stimulation to the vagus nerve.

42. A method of controlling or preventing epileptic seizures comprising the steps of:

- (a) implanting a signal generator in a body of a patient;
- (b) implanting at least one electrode to be communication with a vagus nerve of the body;
- (c) coupling that at least one electrode to the signal generator;
- (d) sensing an electroencephalogram (EEG) of a patient; and

(e) operating the signal generator to enhance desynchronization of EEG rhythms.

43. The method of claim 42, further comprising the step of:

(f) if a possible seizure onset is detected, providing a warning of the possible seizure onset.

44. The method of claim 43, wherein the step of warning includes the step of providing an audio signal.

45. The method of claim 43, wherein the step of warning includes the step of providing a vibrating signal.

46. The method of claim 42, further comprising the steps of:

(f) measuring a characteristic of a heart selected from the group consisting of an instantaneous heart rate (IHR) and a heart rate variability;

(g) determining whether the measured characteristic of the heart is within a normal range; and

(h) if the heart is operating outside the normal range, adjusting stimulation of a vagus nerve to bring the heart within the normal range.

47. A method of controlling or preventing epileptic seizures comprising the steps of:

- (a) implanting a signal generator in a body of a patient;
- (b) implanting at least one electrode to be communication with a vagus nerve of the body;
- (c) coupling that at least one electrode to the signal generator;
- (d) sensing an electrocardiogram (EKG) of a patient for an indication of a possible onset of a seizure; and
- (e) if a possible seizure onset is detected, operating the signal generator to control or prevent the epileptic seizure.

48. The method of claim 47, wherein the step of sensing includes the step of sensing a heart rate.

49. The method of claim 47, wherein the step of sensing includes the step of sensing a rate of change of a heart rate.

50. The method of claim 47, wherein the step of sensing includes the step of sensing R-R variability.

51. The method of claim 47, wherein the step of sensing includes the step of sensing a rate of change of R-R variability.

52. The method of claim 47, wherein the step of sensing includes the step of sensing blood pressure.

53. The method of claim 47, wherein the step of sensing includes the step of sensing a level of oxygen saturation of blood.

54. A method of controlling or preventing epileptic seizures comprising the steps of:

- (a) implanting a signal generator in a body of a patient;
- (b) implanting at least one electrode to be communication with a vagus nerve of the body;
- (c) coupling that at least one electrode to the signal generator;
- (d) sensing an electrocardiogram (EKG) of a patient for an indication of a possible onset of a seizure; and
- (e) if a possible seizure onset is detected, warning the patient of the possible seizure onset.

55. The method of claim 54, wherein the step of sensing includes the step of sensing a heart rate.

56. The method of claim 54, wherein the step of sensing includes the step of sensing a rate of change of a heart rate.

57. The method of claim 54, wherein the step of sensing includes the step of sensing R-R variability.

58. The method of claim 54, wherein the step of sensing includes the step of sensing a rate of change of R-R variability.

59. The method of claim 54, wherein the step of sensing includes the step of sensing blood pressure.

60. The method of claim 54, wherein the step of sensing includes the step of sensing a level of oxygen saturation of blood.

61. A system for controlling or preventing epileptic seizures comprising in combination:

- (a) an implantable signal generator providing stimulation energy;
- (b) at least one electrode having a proximal end coupled to the signal generator and a distal end adapted to provide stimulation energy to a vagus nerve or a patient;
- (c) a sensor for generating a sensor signal indicative of a characteristic of a heart; and
- (d) a control algorithm responsive to the sensor signal for regulating the stimulation by the signal generator to reduce any effects to the heart.

62. The system of claim 61, further comprising:
- (e) a second sensor generating a second sensor signal indicative of a possible onset of a seizure, and wherein the signal generator is responsive to the second sensor signal.
63. The system of claim 62, wherein the second sensor is implantable near a brain of the patient.
64. The system of claim 62, wherein the second sensor is implantable within a brain of the patient.
65. The system of claim 61, wherein the signal generated by the sensor is selected from the group consisting of an instantaneous heart rate (IHR) signal and a heart rate variability signal.
66. The system of claim 61, wherein the signal generated by the sensor is of heart pulse.
67. The system of claim 61, wherein the signal generated by the sensor is an electrocardiogram (EKG) of a patient.

68. The system of claim 61, wherein the control algorithm turns off the stimulation provided by the signal generator in response to the sensor signal indicating an undesired effect on the heart from the vagus nerve.

69. The system of claim 61, further comprising:

- (e) a sensory stimulus responsive to the sensor signal and alerting the patient of an undesired effect on the heart from the vagus nerve.